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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1636
	)	
BRO, et al.	)	Examiner: SCHLAPKOHL, W.
	)	
Serial No.: 10/613,219	)	Washington, D.C.
	)	
Filed: July 7, 2003	)	June 27, 2007
	)	
For: METABOLICALLY ENGINEERED MICRO-ORGANISMS HAVING IMPROVED GALACTOSE UPTAKE	)	Docket No.: BRO=1
	)	Confirmation No.: 7056

PETITION TO VACATE OR WITHDRAW FINALITY

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S i r :

1. Pursuant to 35 USC §1.181, the Applicant requests supervisory review of the office action to determine whether (1) it should be vacated because it misconstrued claim 1 as covering mutants of PGM2 when in fact it does not, or (2) modified to withdraw the imposition of finality in the office action mailed February 27, 2007.

In this action, for the first time, the Examiner argues that a mere mutant of the enzyme PGM2 (even, presumably, one differing from wild-type PGM2 by a single conservative substitution) lacks written description and enablement. While prior rejections questioned the breadth of recitation of enzymes, the Examiner's argument was directed to the coverage of non-PGM2 enzymes which catalyzed the conversion of glucose-1-phosphate to glucose-6-phosphate.

2. As originally filed, the claims related to the use of any enzyme catalysing the conversion of glucose-1 phosphate to glucose-6 phosphate. The only such enzyme identified in the specification was Gal5, which is the product encoded by the *PGM2* gene and which is also known as PGM2.

In the application as filed, claim 7 was directed to a micro-organism which had a gene coding for an enzyme of the defined specificity which was a mutated form of a native enzyme and which thereby had a higher specific activity.

In the first substantive office action of 6th October 2005, only claim 7 attracted a rejection under 35 USC 112 and claims 5 and 6 were objected to for dependency on a rejected claim but were deemed basically allowable. Claim 7 was therefore cancelled.

In the next office action of 22nd May 2006, the conditional allowance of claims 5 and 6 was withdrawn, in view of a newly discovered reference (Weinstock et al). However, in addition to making a prior art rejection, new rejections of lack of written description and enablement were made.

The main claims at this stage were still not limited of course to the PGM2 enzyme. It was urged by the Examiner that the skilled artisan would not have been able to describe the broadly claimed genus of recombinant prototrophic fungi exhibiting an increased galactose uptake and the description was not enabling for 'any enzyme' catalysing the required reaction. It was noted that the prior art disclosed at least four different enzymes catalysing the required conversion and it was urged that the specification was silent as to which phosphoglucomutases will result in increased galactose uptake.

3. It was not specifically objected in the 2006 office action that there was a failure of written description in respect of any PGM2 enzyme. On the contrary, it was reasoned on page 9 of the action that '*The results are not necessarily predictive of any **other** enzyme, **wild type or mutant**, capable of catalyzing the conversion…*'. So the May 22, 2006 rejection was not directed to non-wild type forms of PGM2, but rather to coverage of other enzymes, be they wild type or mutant.

In response to the rejection, the claims were limited to

require PGM2 as the enzyme in question. Note that original claim 3 already presented such a limitation, so the issue of written description for PGM2 was before the Examiner from the beginning.

In the current office action, which has been made final, the claims are rejected under §112 ¶1 on the basis of coverage of (but not a requirement for) a mutant PGM2 enzyme having increased specific activity.

4. As explained in the response proper, claim 1 didn't actually cover mutants of PGM2, and so the office action completely fails to address claim 1 as presented, thus denying, applicants' the benefit of an office action complete under 37 CFR 1.104.

5. Moreover, even if the rejection correctly interpreted claim 1 as covering mutants of PGM2, this would be a new rejection not necessitated by the amendment, PGM2 having been specifically claimed in claim 3. Whilst the present rejection is stated to be a case of maintaining the previous rejection and extending it to newly filed claims 13 and 14, this is not really the case. The rejection as previously raised was different and was plainly overcome by the previous response. <u>At no stage in the prosecution has rejection been raised before under this section against any claim stipulating the use of PGM2 and permitting but not requiring the use of a mutant PGM2 on the basis that the specification does not adequately describe how to obtain the permitted mutant</u>.

Note that none of the instant claims require an increase in specific activity. The previously rejected claim 7 differed materially from the present claims in that it actively <u>required</u> the use of a <u>mutant</u> enzyme with <u>higher specific activity and</u> in that it was not restricted to mutants of PGM2.

The May 22, 2006 written description rejection appears at

pages 6-11 of that office action. At page 8, the Examiner briefly noted that the specification taught that the enzyme could be higher specific activity mutants of wild type enzymes. On page 9, we have the previously quoted "other enzyme, wild type or mutant" language. Nowhere did the Examiner state that there is a lack of written description for mutants of PGM2, as distinct from non-PGM2 enzymes.

The Examiner states that he has considered the Applicant's arguments on written description of PGM2 mutants carefully. In reality, the Applicant has not previously argued this point. The only time a rejection directed to the coverage of mutants (of a broader class of enzymes) was raised, the Applicant cancelled the relevant claim (claim 7) without argument.

This is in reality a new rejection not necessitated by any amendment of the claims made by the applicant and the finality of this office action should be withdrawn.

6. The May 22, 2006 enablement rejection appears at pages 11-17 of that office action. At page 11, the Examiner concedes enablement for "wild type PGM2", which could have been a prelude for an attack on enablement of mutant PGM2.

However, the Examiner did not go on to point out any enablement problems with mutants of PGM2 (even though original claim 3 recited "PGM2"). Instead, he discussed non-PGM2 enzymes, notably AGM, PGM1 and PMM (see page 14). Hence, the Applicant was not put on notice that the Examiner had a problem with PGM2 mutants. Moreover, even if the reference to "wild-type PGM2" was deemed to constitute such notice, it was still incumbent on the Examiner to make out a prima facie case that PGM2 mutants were not enabled, and since no argument was made concerning PGM2 mutants, the presumption of enablement established by In re Marzocchi certainly was not overcome.

We conclude that the "PGM2 mutant" enablement rejection

is likewise a new ground of rejection not necessitated by our amendments (cp. claim 3), and hence finality should be withdrawn.

Respectfully submitted,

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